§ 201.58 Requests for waiver of requirement for adequate and well-controlled studies to substantiate certain labeling statements.

A request under § 201.57(b)(2)(ii), (c)(2), (c)(3)(i), (c)(3)(v), (f)(9), and (g)(4) for a waiver of the requirements of § 314.126(b) of this chapter shall be submitted in writing as provided in § 314.126(b) to the Director, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20587, or, if applicable, the Director, Center for Biologics Evaluation and Research, 8800 Rockville Pike, Bethesda, MD 20892. The waiver shall be granted or denied in writing by such Director or the Director's designee.

[55 FR 11576, Mar. 29, 1990]

§ 201.59 Effective date of §§ 201.56, 201.57, 201.100(d)(3), and 201.100(e).

(a) On and after December 26, 1979, no person may initially introduce or initially deliver for introduction into interstate commerce any drug to which §§ 201.56, 201.57, 201.100(d)(3) apply unless the drug's labeling complies with the requirements set forth in the regulations, with the following exceptions:

(1) If the drug is a prescription drug that is not a biologic and not subject to section 505 of the act (21 U.S.C. 355), and was not subject to former section 507 of the act (21 U.S.C. 357, repealed 1997), §§ 201.56, 201.57, and 201.100(d)(3) are effective on April 10, 1981.

(2) If the drug is a prescription drug that on December 26, 1979 is (i) a licensed biologic, (ii) a new drug subject to an approved new drug application or abbreviated new drug application under section 505 of the act or (iii) an antibiotic drug subject to an approved antibiotic form, §§ 201.56, 201.57, and 201.100(d)(3) are effective on the date listed below for the class of drugs to which the drug belongs. Dates are also listed below for the submission of supplemental applications, amendments, and license changes.

(3) If the drug is approved after December 26, 1979 but is a duplicate of a drug approved on or before that date (for example, a drug approved under an abbreviated new drug application or an antibiotic form), §§ 201.56, 201.57, and 201.100(d)(3) are effective on the date listed below for the class of drugs to which the drug belongs. Dates are also listed below for the submission of supplemental applications, amendments, and license changes.

Effective	Revised labeling due	Drug class	Mail routing code
		BIOLOGICS	
Nov. 1, 1982	Nov. 1, 1980	Bacterial vaccines and antigens with no U.S. standard of potency.	HFB–240
Do	do	Skin test antigens	HFB–240
Nov. 1, 1982 [1]	Nov. 1,1980 [2]	Bacteral vaccines and toxoids with standards of potency.	HFB–240
Do	do	Viral and rickettsial vaccines	HFB–240
Do	do	Allergenic extracts	HFB–240
Do	do	Blood and blood derivatives	HFB–240
		NEW DRUGS AND ANTIBIOTIC DRUGS	
Nov. 1, 1982	Nov. 1, 1980	Antiarrhythmics	HFD–110
Do	do	Replenishers and regulators of electrolytes and water balance	HFD–110, HFD–510, and HFD–160
Do	do	Anticonvulsants	HFD–120
Do	do	Adrenal corticosteroids	HFD–510 and HFD–150
Do	do	Aminoglycosides	HFD–520
Do	do	Scabicides	Do.
Do	do	Pediculicides	Do.
Do	do	General anesthetics	HFD–160
Dec. 1, 1982	Dec. 1, 1980	Antivirals	HFD–520
Do	do	Dermatologics	Do.
Jan. 1, 1983	Jan. 1, 1981	Glaucoma ophthalmics	HFD–520
Do	do	Topical otics	Do.
Feb. 1, 1983	Feb. 1, 1981	Antispasmodics	HFD–110
Do	do	Anticholinergics	Do.
Do	do	Diuretics	Do.
Do	do	Narcotic antagonists	HFD–120
Do	do	Alcohol antagonists	Do.